K073687

SECTION 3

Summary of Safety and Effectiveness

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Sponsor:	EMcision, Ltd.
Contact Person:	Nagy Habib, MD Chief Executive Officer Liver Surgery Section, Hammersmith Hospital Du Cane Road London, W12 0NN United Kingdom
Summary Prepared:	August 20, 2007
Trade Name:	Habib Laparoscopic Hexablate
Common Name:	Electrosurgical cutting and coagulation device and accessories
Classification:	Class II per 21 CFR 878.4400
Product Code:	GEI
Predicate Devices:	Habib Hexablate (K071103) - EMcision Habib 4X Laparoscopic (K062935) RITA Medical

Intended Use:

The Habib Hexablate is intended to be used to assist in coagulation of tissue during laparoscopic intraoperative surgical procedures.

Description:

The Habib Laparoscopic Hexablate is a bipolar radiofrequency (RF) device that consists of a handle, laparoscopic shaft and introducer and an array of seven parallel electrodes which extend out from the laparoscopic shaft. The electrode configuration consists of six electrodes in a ring and one electrode in the center of the ring. The Habib Laparoscopic Hexablate has an attached cable which connects the device to the Habib Hexablate Switch Unit and then to an RF Generator. The electrodes are inserted into tissue and the tissue is coagulated using RF power. The Habib Laparoscopic Hexablate is designed for use in laparoscopic surgery and is a single use device.

Technological Differences:

The Habib Laparoscopic Hexablate has the same basic technological characteristics as the Habib Hexablate (K071103). Both devices use bipolar RF energy through a number of electrodes to create a volume of coagulated tissue. The primary difference is that the Habib Laparoscopic Hexablate is used via a laparoscopic port. The size and shape of the coagulation zone created by each device is similar. Both devices uses aspiration through the center electrode to remove fluids and gases from the center of the coagulation zone.

The Laparoscopic Hexablate is fitted with an introducer which allows the electrodes to pass through a standard Ø12mm laparoscopic port without damaging the seals.

The Habib 4X Laparoscopic (K062935) has the same basic technological characteristics as the Habib Laparoscopic Hexablate. Both devices use bipolar RF energy through a number of electrodes to create a volume of coagulated tissue during laparoscopic procedures. The primary difference is that the Habib 4X Laparoscopic and the Habib Laparoscopic Hexablate is the number of electrodes. The Habib 4X Laparoscopic has 4 electrodes on a fixed 10mm diameter, whilst the Habib Laparoscopic has 7 electrodes (six outer array and 1 centre) which deploy upon exit of the introducer port to 20mm diameter.

Performance Data:

Performance testing was done to ensure that the Habib Laparoscope Hexablate functions as intended and meets design specifications. Sufficient data was obtained to show that the device is substantially equivalent to the predicate device, and meets safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2008

EMcision, Ltd
% Underwriters Laboratories, Inc.
Mr. Morten Simon Christensen
455 East Trimble Road
San Jose, California 95131

Re: K073687
Trade/Device Name: Habib Laparoscopic Hexablate
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 27, 2007
Received: December 28, 2007

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(K) Number (if known) K073687

Device Name Habib Laparoscopic Hexablate

The Habib Laparoscopic Hexablate is intended to be used to assist in coagulation of tissue during laparoscopic intraoperative surgical procedures

Prescription Use ✓ OR Over the Counter Use _____
(per 21 CFR 801.109)

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073687